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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,383	05/03/2005	Stanley George Bonney	P33144USW	3387

23347 7590 09/04/2008

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EXAMINER	
OSTRUP, CLINTON T	
ART UNIT	**PAPER NUMBER**
3771	

NOTIFICATION DATE	DELIVERY MODE
09/04/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/534,383	BONNEY ET AL.	
	Examiner	Art Unit	
	CLINTON OSTRUP	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6,9-22,24-29,31-33 and 36-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6,9-22,24-29,31-33 and 36-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 3-4, 6, 9-22, 24-29, 31-33, and 36-42 are pending in this application.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3-4, 6, 9-10, 13-22, 24-28, 31-33, 36-37, and 40-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al., 5,069,204.

Regarding claims 1 and 33, Smith discloses a hand-operated drug delivery device (figure 4) that is used for delivering to a patient a drug composition from a container (6) which contains the drug composition, the container adapted to be placed in a dispensing mode thereof on application of an actuating condition (pressing down on 6) thereto which comprises movement of a first part (vial) of the container relative to a second part (valve stem 8) of the container, the device comprising: a dispensing unit (2) adapted to receive the container, the dispensing unit having an actuating mechanism (pressing down on 6) hand-operable to apply the actuating condition to the container and an outlet (12) through which the drug composition is dispensable from the device, the actuating mechanism configured to hold the second part of the container (valve stem 8) stationary and to allow the first part (vial 6) to move relative thereto for dispensing the drug composition from the container; and a casing unit (34) for the dispensing unit, the casing unit configured to be movable between a closed state (figure

4) in which the casing covers the outlet, and an open state (figure 5) in which the casing unit uncovers the outlet; and wherein: the dispensing and casing units have securing features (44 & 46) fixedly securing the units together; the actuating mechanism is hand-operable to apply the actuating condition to the container when the dispensing unit is fixedly secured to the casing unit with the casing unit in the open state, but not the closed state; the securing features are adapted to releasably secure the casing unit (col. 5, lines 28-35) and the dispensing unit together so that the casing unit is removable from the dispensing unit; in the closed state, the casing unit is configured to enclose the dispensing unit (figure 4) with the container received therein; and the dispensing unit is hand-operable to apply the actuating condition to the container (by pressing on 6) when the dispensing unit is independent from the casing unit.

Regarding claim 3, the device (figure 4) disclosed by Smith is hand-held.

Regarding claim 4, Smith discloses a device that is adapted to be held by the casing unit when assembled with the dispensing unit. See: figure 4.

Regarding claim 6, Smith discloses a device that is adapted so that, when the casing unit is held by a hand of a patient, the hand of the patient is also able to operate the actuating mechanism of the dispensing unit (i.e. the device of Smith is adapted do that if a hand holds 34 it can also actuate the device).

Regarding claim 9, Smith discloses a device with a container that has a plurality of doses of a drug composition and the device has a dose counter mechanism wherein the dispensing unit (2) has a dose Counter advancing mechanism (26) adapted to

advance the dose counter mechanism (26) when an actuating condition is applied by the dispensing unit to the container. See: col. 3, lines 28-33 and col. 4, lines 61-68.

Regarding claim 10, Smith discloses a device with a dose counter advancing mechanism (26) has a mechanical feature (28) which engages the dose counter mechanism to advance it on relative movement of the first part of the container to the second part.

Regarding claim 13, Smith discloses a device in which an outlet (12) forms part of a nozzle arrangement (4) in the dispensing unit for directing the drug composition to the patient on application of the actuating condition to the container.

Regarding claim 14, Smith discloses a device wherein the second part (valve stem) of the container presents an outlet of the container (6).

Regarding claim 15, Smith discloses a device wherein the outlet of the container (valve stem) is held stationary by the nozzle arrangement (10).

Regarding claim 16, Smith discloses a device wherein the second part (valve stem) is a part of the valve which is moved between a closed position (not actuating) and an open position (when actuated) on relative movement with the first part (vial).

Regarding claim 17, Smith discloses a device with a container (6) that is an aerosol container (see: col. 3, lines 65-67) with the first part a canister (vial).

Regarding claim 18, Smith discloses a device with a container (6) comprising a drug composition therein. See: col. 1, lines 5-14.

Regarding claim 19, Smith discloses a device with a drug composition that is used for the treatment of respiratory diseases or disorders. See: col. 1, lines 16-68.

Regarding claim 20, Smith discloses a device used for inhalation (i.e. it is an inhaler).

Regarding claim 22, Smith discloses a method of manufacturing a hand-operated drug delivery device (figure 4) for delivery of a drug formulated in a drug container (6) which is adapted to be placed in a dispensing mode on application of an actuating condition thereto which comprises movement of a first part of the container (vial) relative to a second part (valve stem) of the container, the method comprising the steps of: providing a dispensing unit (2) for receiving the container (6), the dispensing unit having an actuating mechanism (pressing down on 6) hand-operable to apply the actuating condition to the container and an outlet (12) through which the drug formulation is dispensed on application of the actuating condition to the container, the actuating mechanism configured to hold the second part (valve stem) of the container stationary and to allow the first part (vial) to move relative thereto for dispensing the drug composition from the container (6); and separately providing a casing unit (34) adapted to fixedly hold the dispensing unit (2) such that the drug is dispensable from the container (6) by the dispensing unit when held by the casing unit, the casing unit configured to be movable between a closed state (figure 4) in which the casing covers the outlet, and an open state (figure 5) in which the casing unit uncovers the outlet; and wherein: the dispensing and casing units have securing features (44 & 46) for fixedly securing the units together; the actuating mechanism is hand-operable to apply the actuating condition to the container (6) when the dispensing unit is fixedly secured to the casing unit with the casing unit in the open state, but not the closed state; the

securing features are adapted to releasably secure the casing unit and the dispensing unit together (see: col. 5, lines 28-35) so that the casing unit is removable from the dispensing unit; in the closed state the casing unit is configured to enclose the dispensing unit with the container received therein; and the dispensing unit is hand-operable to apply the actuating condition to the container when the dispensing unit is independent from the casing unit (by pressing down on 6).

Regarding claim 24, the device (figure 4) disclosed by Smith is hand-held.

Regarding claim 25, Smith discloses the dispensing unit as being provided with at least a part of a dose counting mechanism (26).

Regarding claim 26, Smith discloses a drug container has a dose counter (26) and the dispensing unit has a dose counter advancing mechanism (28) for advancing the dose counter on application of the actuating condition.

Regarding claim 27, Smith discloses a dose counter advancing mechanism (26) as a mechanical mechanism (it is advanced by actuation of the dispenser).

Regarding claim 31, Smith discloses a dispensing unit that has a valve stem support (10) for receiving a valve stem (8) of a valve mechanism of the container, relative movement of the container (6) to the dispensing unit causing depression of the valve stem for release of a dose of the drug from the container.

Regarding claim 32, Smith discloses the outlet (12) of the dispensing unit is an exhaust duct (via 4) for channeling the drug to the external environment when released from the container.

Regarding claim 36, Smith discloses a casing unit that contains a container member (cavity formed by 34 holding inhaler shown in figure 1) cavity holding which defines a cavity in which the dispensing unit is releasably, fixedly securable (see: col. 5, lines 28-35), and a cover member (38) which is movably mounted on the container member for movement between closed (figure 4) and open (figure 5) positions relative to the cavity to respectively place the casing unit in the closed and open states.

Regarding claim 37, Smith discloses a cover member that is adapted to cover the outlet (4) of the dispensing unit in the closed position and to uncover the outlet in the open position.

Regarding claim 40, Smith discloses a device wherein the dispensing unit (2) is adapted to receive the container (6) such that the first part (vial) protrudes therefrom.

Regarding claim 41, Smith discloses a device wherein the casing and dispensing units are releasably and fixedly secured together, optionally with a container received in the dispensing unit. See: col. 5, lines 28-35.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 21, 38, 39 & 42 are rejected under 35 U.S.C. 103(a) as being obvious over Smith et al., (5,069,204) as applied to claims 1, 18, and 36 above.

Smith discloses all the limitations of claim 21 except the at least one further dispensing unit and the dispensing units being interchangeable with one another as claimed.

Since Smith discloses an outer casing that removably retains conventional inhalers, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have removed an empty medicament conventional inhaler from the case and replaced it with a full medicament containing conventional inhaler in order to provide a refilled case for delivering medicament to a user.

Regarding claim 38, Smith contemplates for different sized vials and provides an aperture in the case for allowing the vials to extend. See: col. 3, lines 15-27 and figures 8a & 8b. Thus, Smith teaches a device with a dispensing unit that is adapted to receive a container such that the first part (vial) is accessible to a digit of a patient's hand (via the aperture) to enable the digit to move the first part relative to the second part and wherein the casing unit is adapted such that when fixedly secured with the dispensing unit, and in the open state, the first part of the container is accessible to the digit of the patient's hand to enable the digit to move the first part relative to the second part.

Regarding claim 39, Smith teaches a cover member (38) that is adapted to cover the first part of the container (8) when in the closed position (figure 4) and to uncover the first part when in the open position (figure 5).

Regarding claim 42, Smith contemplates for different sized vials and provides an aperture in the case for allowing the vials to extend. Thus, Smith teaches a dispensing unit that is adapted to receive the container (6) such that the first part is accessible to a

digit of a patient's hand (via the aperture) to enable the digit to move the first part relative to the second part and wherein the casing unit is adapted such that when fixedly secured with the dispensing unit, and in the open state (figure 5), the first part of the container (vial) is accessible to the digit of the patient's hand to enable the digit to move the first part relative to the second part (by actuating the container).

6. Claims 11-12 & 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al., (5,069,204) as applied to claims 1, 9-10, 22 & 26 above, and further in view of Rand et al., (6,431,168).

Smith discloses all the limitations of claims 11-12 & 28-29 except the post and rack-and-pinion dose counter mechanism.

Rand et al., teach an inhaler comprising an external housing (1) with a counter mechanism (13) wherein the first member comprises a pinion carried by a shaft through the lost motion coupling and the second member comprises a rack, thus meeting the counter mechanism as claimed in claims 9-12 and 26-29. The Rand et al., reference teaches that the dispensing mechanism is useful in the treatment of respiratory disorders and that the counter allows the user to view the number of doses remaining in the container before the contents have been exhausted. Moreover, the Rand et al., reference teaches that metered dose inhalers are well known for delivering medicaments to the mouth and the nose for treatment of respiratory disorders. See: page 1, lines 1-34; page 4, lines1-9; page 5, lines 24-35; page 6, lines 26-33 and Figures 1 and 7.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have substituted the dose counter mechanism of Smith with the dose counter mechanism taught by Rand et al., because of the reasonable expectation that one dose counter mechanism could be substituted for another and would perform equally well for determining the number of doses administered or left in a metered dose drug delivery device.

Response to Arguments

Applicant's arguments with respect to claims 1, 3-4, 6, 9-22, 24-29, 31-33, and 36-42 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771